

116TH CONGRESS  
1ST SESSION

# H. R. 4913

To amend title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 30, 2019

Mr. MCKINLEY (for himself and Ms. KUSTER of New Hampshire) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1     **SECTION 1. REQUIREMENTS FOR PDP SPONSORS OF PRE-**  
2                 **SCRIPTION DRUG PLANS UNDER PART D OF**  
3                 **THE MEDICARE PROGRAM THAT USE**  
4                 **FORMULARIES.**

5         (a) IN GENERAL.—Section 1860D–4(b)(3) of the So-  
6         cial Security Act (42 U.S.C. 1395w–104(b)(3)) is amend-  
7         ed by adding at the end the following new subparagraphs:

8                 “(I) REQUIRED INCLUSION OF CERTAIN  
9                 GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL  
10                 PRODUCTS.—

11                 “(i) IN GENERAL.—With respect to a  
12                 plan year beginning on or after January 1,  
13                 2021, the formulary shall include—

14                 “(I) each covered generic drug  
15                 for which the wholesale acquisition  
16                 cost is less than the wholesale acqui-  
17                 sition cost of the reference drug of such  
18                 covered generic drug; and

19                 “(II) each covered biosimilar bio-  
20                 logical product for which the whole-  
21                 sale acquisition cost is less than the  
22                 wholesale acquisition cost of the ref-  
23                 erence biological product of such cov-  
24                 ered biosimilar biological product.

25                 “(ii) PROHIBITION ON CERTAIN LIM-  
26                 ITS ON ACCESS.—The PDP sponsor offer-

1                         ing the prescription drug plan may not im-  
2                         pose limits on access to a covered generic  
3                         drug required to be included on the for-  
4                         mulary under clause (i)(I) or a covered  
5                         biosimilar biological product required to be  
6                         included on the formulary under clause  
7                         (i)(II), including through prior authoriza-  
8                         tion, utilization management, or step ther-  
9                         apy, that are more restrictive than any  
10                         such limits imposed on access to the ref-  
11                         erence drug of such covered generic drug  
12                         or reference biological product of such cov-  
13                         ered biosimilar biological product, respec-  
14                         tively, or that otherwise have the effect of  
15                         giving preferred status to such reference  
16                         drug or reference biological product over  
17                         such covered generic drug or covered bio-  
18                         similar biological product, respectively.

19                         “(iii) DEFINITIONS.—In this subpara-  
20                         graph and subparagraph (J):

21                         “(I) COVERED BIOSIMILAR BIO-  
22                         LOGICAL PRODUCT.—The term ‘cov-  
23                         ered biosimilar biological product’  
24                         means a covered part D drug that is

1                   a biosimilar biological product (as de-  
2                   fined in section 1847A(c)(6)(H)).

3                   “(II) COVERED GENERIC  
4                   DRUG.—The term ‘covered generic  
5                   drug’ means a covered part D drug  
6                   that is a drug described in section  
7                   1860D–2(e)(1)(A) and approved  
8                   under section 505(j) of the Federal  
9                   Food, Drug, and Cosmetic Act.

10                  “(III) REFERENCE BIOLOGICAL  
11                  PRODUCT.—The term ‘reference bio-  
12                  logical product’ has the meaning given  
13                  such term in section 1847A(c)(6)(I).

14                  “(IV) REFERENCE DRUG.—The  
15                  term ‘reference drug’ means, with re-  
16                  spect to a covered generic drug, the  
17                  listed drug (as described in clause (i)  
18                  of section 505(j)(2)(A) of the Federal  
19                  Food, Drug, and Cosmetic Act) that  
20                  is referred to in the abbreviated appli-  
21                  cation for such covered generic drug  
22                  under such section.

23                  “(V) WHOLESALE ACQUISITION  
24                  COST.—The term ‘wholesale acqui-

1    tion cost' has the meaning given such  
2    term in section 1847A(c)(6)(B).

3   “(J) COST-SHARING TIERING REQUIRE-  
4   MENTS WITH RESPECT TO COVERED GENERIC  
5   DRUGS AND COVERED BIOSIMILAR BIOLOGICAL  
6   PRODUCTS.—

7   “(i) GENERIC DRUG COST-SHARING  
8   TIER.—With respect to a plan year begin-  
9   ning on or after January 1, 2021, the  
10                                        PDP sponsor offering the prescription  
11                                        drug plan shall—

12   “(I) have at least one cost-shar-  
13   ing tier on the formulary that only in-  
14   cludes covered generic drugs and cov-  
15   ered biosimilar biological products;  
16   and

17   “(II) apply a cost-sharing re-  
18   quirement with respect to each cost-  
19   sharing tier described in subclause (I)  
20   on the formulary that is meaningfully  
21   lesser than the lowest cost-sharing re-  
22   quirement applicable with respect to  
23   any cost-sharing tier on such for-  
24   mulary that includes a brand drug  
25   (referred to in this subparagraph as

1                   the ‘lowest brand drug cost-sharing  
2                   tier’).

3                   “(ii) SPECIALTY GENERIC DRUG COST-  
4                   SHARING TIER.—With respect to a plan  
5                   year beginning on or after January 1,  
6                   2021, if the PDP sponsor offering the pre-  
7                   scription drug plan has a cost-sharing tier  
8                   for specialty brand drugs on the formulary,  
9                   the PDP sponsor shall—

10                  “(I) have a cost-sharing tier on  
11                  such formulary that only includes cov-  
12                  ered generic drugs and covered bio-  
13                  similar biological products—

14                  “(aa) for which the whole-  
15                  sale acquisition cost is greater  
16                  than a threshold specified by the  
17                  Secretary; and

18                  “(bb) with respect to which  
19                  the reference drug for such a  
20                  covered generic drug or the ref-  
21                  erence biological product for such  
22                  a covered biosimilar biological  
23                  product is either included on a  
24                  cost-sharing tier on such for-  
25                  mulary with a cost-sharing re-

1   requirement that is greater than  
2   the cost-sharing requirement ap-  
3   plied under subclause (II), or ex-  
4   cluded from such formulary; and  
5   “(II) apply a cost-sharing re-  
6   quirement with respect to the cost-  
7   sharing tier required for the for-  
8   mulary under subclause (I) that is  
9   meaningfully lesser than the cost-  
10   sharing requirement applicable with  
11   respect to the cost-sharing tier for  
12   specialty brand drugs on such for-  
13   mulary.

14   “(iii) PLACEMENT OF CERTAIN GE-  
15   NERIC DRUGS AND BIOSIMILAR BIOLOGI-  
16   CAL PRODUCTS.—Each covered generic  
17   drug and each covered biosimilar biological  
18   product required to be included on the for-  
19   mulary under subparagraph (I)(i) shall be  
20   included either on a cost-sharing tier de-  
21   scribed in clause (i)(I) or, if applicable, the  
22   cost-sharing tier required for the formulary  
23   under clause (ii)(I).

24   “(iv) DEFINITIONS.—In this subpara-  
25   graph:

1                         “(I) BRAND DRUG.—The term  
2                         ‘brand drug’ means a covered part D  
3                         drug that is a drug described in sec-  
4                         tion 1860D–2(e)(1)(A) and approved  
5                         under section 505(c) of the Federal  
6                         Food, Drug, and Cosmetic Act.

7                         “(II) MEANINGFULLY LESSER.—  
8                         The term ‘meaningfully lesser’  
9                         means—

10                         “(aa) for purposes of sub-  
11                         clause (II) of clause (i), such a  
12                         lesser cost-sharing requirement  
13                         that the Secretary determines  
14                         will likely significantly incentivize  
15                         the utilization of covered generic  
16                         drugs and covered biosimilar bio-  
17                         logical products on a cost-sharing  
18                         tier described in subclause (I) of  
19                         such clause on a formulary over  
20                         covered part D drugs on the low-  
21                         est brand drug cost-sharing tier  
22                         on such formulary; and

23                         “(bb) for purposes of sub-  
24                         clause (II) of clause (ii), such a  
25                         lesser cost-sharing requirement

1                   that the Secretary determines  
2                   will likely significantly incentivize  
3                   the utilization of covered generic  
4                   drugs and covered biosimilar bio-  
5                   logical products on the cost-shar-  
6                   ing tier required for the for-  
7                   mulary under subclause (I) of  
8                   such clause over covered part D  
9                   drugs on the cost-sharing tier for  
10                  specialty brand drugs on such  
11                  formulary.

12                 “(III) SPECIALTY BRAND  
13                 DRUG.—The term ‘specialty brand  
14                 drug’ means a brand drug for which  
15                 the wholesale acquisition cost is great-  
16                 er than a threshold specified by the  
17                 Secretary.”.

18                 (b) CONFORMING AMENDMENT.—Section 1860D–  
19                 2(b)(2)(B) of the Social Security Act (42 U.S.C. 1395w–  
20                 102(b)(2)(B)) is amended by inserting before the period  
21                 the following: “and section 1860D–4(b)(3)(J)”.

